TITLE

"AUTOMATIC APPARATUS FOR CONTROLLING THE CHILDBIRTH LABOUR"

SPECIFICATION

The present invention refers to an automatic apparatus for controlling the childbirth labour.

It is known that the term "childbirth labour" refers to the complex of mechanical and dynamic phenomena which lead to the expulsion of the fetus and placenta and which, conventionally, is subdivided into three stages:

- the first stage, which relates to the dilatant period, that is, to the beginning of the labour up to the complete dilatation of the uterine cervix, is in turn subdivided into a "latent period", characterized by a dilatation of 3-4 cm, and a following "active period" which leads to a complete dilatation;
- the second stage, which relates to the expulsive period, goes from the complete dilatation to the delivery;
- the third stage, which relates to the discharge of the after-birth, ends up with the expulsion of the placenta.

It is also known that the deficiency, alteration or insufficient coordination of the uterine contractions may cause problems upon the expulsive stage, which is the delivery's most delicate one. In particular, it may happen that the uterus is not able to produce, with its contractions, a force of an intensity sufficient to conclude the delivery's expulsive stage (hypokinesia). It may happen, besides, that the expectant mother, in spite of the therapies commonly provided for treating such cases, is unable to produce a thrust - through a corresponding contraction of the abdominal press - adding up to the force generated by the uterine contraction. And, since a prolonged rest of the fetus in the delivery duct may seriously endanger the health

condition thereof, a so-called Kristeller manoeuvre is generally performed by the health personnel, which consists in exerting, with an arm, a series of thrusts upon the bottom of the uterus, with the purpose of assisting the natural expulsive forces and speeding up the progression and disengagement of the fetus. However, this manoeuvre has risks inasmuch as it may cause the rupture of the uterus, the detachment of the placenta and acute fetal pains as well.

Also known in obstetrics is the use of the electromyograph (EMG) by which it is possible to register the electrical phenomena of the uterus' natural and involuntary contractions by deriving the relevant electrical potentials via electrodes applied on the patient's abdomen: an application software to be run on a PC provides for a graph of said electrical potentials versus time. However, the use of only an EMG does not provide any aid to the parturient's thrust and, moreover, the contraction graphs plot also other spurious signals such as spikes, tensions induced by the activation of other apparatuses and by neon glow lamps.

Also known in obstetrics is the use of the Pressure Labor Assister (PLA), with pressure sensors-controlled software, which utilizes the pressure increase inside an air chamber - formed within an abdominal band fixed around the patient's body - and which occurs as a consequence of the natural uterine contractions, to provide an automatic extra force, as an aid to the parturient, for the expulsion of the future baby.

On the other hand, this known device PLA does not provide a chart nor a record of the uterine contractions, and may also be a source of dangers, inasmuch as the possible overpressures on the pneumatic band, which are independent of the contractions but are due instead, for example, to more or

less involuntary movements of the parturient, are always interpreted as a signal of uterine contraction and, in such case, it may occur that the consequent inflation of the abdominal pneumatic band will take place during a rest period, between one contraction and another, thereby dangerously reducing the inflow of blood to both the parturient and future baby.

One object of the present invention is to overcome the drawbacks of the common and widespread Kristeller technique.

A further object of the present invention is to enable, in case of ascertained insufficient expulsive force of the uterine natural contractions, the person in charge of the childbirth to activate a device providing an extra thrust for the expulsion of the fetus - the activation of said device depending, for a higher safety measure, on the uterine contraction and not on false signals.

This result has been achieved, according to the invention, by adopting the idea of making an apparatus having the characteristics disclosed in the independent claims. Further characteristics being set forth in the dependent claims.

The advantages deriving from the present invention lie essentially in the fact that it is possible to automatically ensure, whenever the need arises and in a non-invasive fashion, the highest accurate coordination between the internal thrust produced by both natural and involuntary uterine contractions and the supplementary thrust produced by means of a pneumatic belt intended to act on the parturient's abdomen; that an apparatus according to the invention is safe, utilizable with relative simplicity by the personnel assisting the expectant mothers, relatively simple to make and reliable also after a prolonged service period. All this by making use of an integrated system allowing the auxiliary

pneumatic thrust to be obtained only when the parturient has contractions detected simultaneously and safely by both pneumatic and electrical signals independent from each other and deriving from said contractions.

These and other advantages and characteristics of the invention will be best understood by anyone skilled in the art from a reading of the following description in conjunction with the attached drawings given as a practical exemplification of the invention, but not to be considered in a limitative sense, wherein:

- Fig. 1 is a simplified block diagram of an apparatus according to the invention, showing a possible configuration thereof upon use;
- Fig. 2 is a schematic plan view of the pneumatic belt (1) shown in the schematic diagram of Fig. 1;
- Fig. 3 is a further simplified block diagram of an apparatus according to the invention.

Reduced to its basic structure, and reference being made to the figures of the attached drawings, an apparatus for controlling the childbirth labour, according to the invention, comprises:

- means for detecting the electrical activity of the uterus, comprising two or more outer electromiographic sensors (3) (that is, sensors of non-invasive type) able to be positioned on the skin of the parturient's abdomen at two regions corresponding to preset points of the uterus U;
- means for registering and plotting the electrical signals of the uterine contractions thus detected;
- means (4, 5) for analysing said electrical signals in relation to a predetermined scheme of analysis;
- an inflatable belt (1) associated with pneumatic means (2) able to inflate it under control and at preset pressure, and

respectively deflate it: the said belt (1) being put on by the expectant mother in such a way that a surface (10) of the same belt will act, when inflated, upon the bottom of the uterus;

- means (7) to control the activation and deactivation of said pneumatic means (2) in response to the pressure variation due to the contraction and sensed by the pneumatic belt, and to the result of analysis of the uterus' electrical activity.

In particular, the said analysis means comprise an electromyographic apparatus (4), associated with said sensors (3) via an interface (5) allowing the amplification and pre-processing of the signals and provided with a section (6) for processing the signals detected by the sensors (3) and transmitted through the interface (5) with their respective time value, as best described later on in greater details.

In case of two-channel electromyographic apparatuses, such as the TECA Sinergy Multimedia of the Oxford Instruments, two channel sensors or electrodes and one ground electrode are used: the channel sensors are positioned simmetrically and horizontally in a skin region of the parturient's abdomen at about 5-15 cm of the umbilical transverse, and the ground electrode is located on the internal side of the left thigh.

As for the said inflatable belt (1), this is of a type comprising an air chamber (11) with a coupling (12) for a tube (13) connectable to said means (2), and provided with two wings (14) of a length sufficient for being tied up around the parturient's thorax: the said wings (14) being able to be linked one to the other by "velcro"-type means 140 after the belt has put on. Moreover, the pneumatic means (2) is internally provided with sensors (15) able to detect the pressure variations inside the air chamber (11), which are

due to the thrusts exerted by the parturient's abdomen as a consequence of the uterine contractions, that is, relative to a basic pressure value corresponding to the initial inflation (for example, when using a belt of MITECH-200-A type, a basic value of 8-16 kPa). The belt in question is intended to exert, as best described later on, a predetermined pressure P uniformly distributed on the uterus' bottom.

Provided upstream of said pneumatic means (2) is an activation device (7) which, in turn, is associated with sensors (15) located within the means (2), and with the electromyographic apparatus (4): said device (7) determining the activation of the pneumatic means (2), that is, the inflation of the belt (1), whenever both the uterine contraction signals on output from the sensors (15) and the signals on output from the apparatus (4) are present therein at the same time.

To be more precise, if, during the labour, the device (7) receives simultaneously both the electrical signals from the means (4) - resulting of such intensity and shape as to correspond to those of the uterine contractions (for example, electrical signals three times higher than the signals sensed between one contraction and another) - and the pneumatic signals detected by the sensors (15) and identified as contraction signals as well, then, only in this case the said device (7) gives the command for the activation of the means (2), that is, for the inflation of the belt (1) at a pressure to be either preset or timely established by the person in charge of the childbirth.

In other words, the activation of belt (1) and, accordingly, the auxiliary thrust P exerted by the latter on the parturient's abdomen in correspondence of the uterus' bottom, takes place solely when there is occur, simultaneously, on

the one hand, an overpressure in the chamber (11) of belt (1) due to a deformation imposed by the abdominal muscles on the belt's wall because of a contraction and, on the other hand, that is, in correspondence of sensors (3), a myoelectrical activity of preset intensity and in any case exceeding the intensity being present when no contractions occur. The two detections are independent from each other, as being obtained from independent detection means, but are both related to a same event, that is, to the natural and involuntary uterine contraction upon the active stage of the childbirth. It thus follows that the actuation of the belt (1) results precisely in phase with the uterine contractions of greater intensity, as it is operated on the basis of detections made both within the chamber (11) of belt (1) and on the basis of detections made on the muscular electrical activity in the more directly involved abdominal region.

The time for the activation of belt (1), that is, the time of overpressure persistence within the chamber (11) of the same belt under control of means (2), is adjustable by the health operator who assists the expectant mother and whose decisions are taken according to the trend of the electromyographic contraction signals previously registered for the same patient.

As above described, the device (7) which controls the activation of the means (2) provided for the inflation of the belt (1)is commonly associated with the pressure sensors (15) and with the electrical sensors (3) as well. However, the operator may cut off one or the other connection, owing to a malfunction of one of them or when he/she deems suited to do so.

For example, it is possible to exclude the connection with the pressure sensors (15) so that the activation of the

pneumatic means (2) be controlled solely by electrical signals transmitted by the sensors (3); otherwise, it is possible to cut off the sensors (3), so that the activation of the pneumatic means (2) be controlled solely by pressure signals transmitted by the sensors (15). All this makes it possible to use the device in question also in case of malfunctions affecting either the detection of pressure signals through the sensors (15) or the detection of signals transmitted by the sensors (3), and to process the signals by means of the electromyographic apparatus (4, 6).

In any case, the operator has faculty of excluding the automatic intervention of the system in order to use the latter only when the need arises.

With reference to the diagram of Fig. 3, the said device (7) comprises an AND gate (70) whose inputs are connected, respectively, to the output of the apparatus (4) and to the output of an A/D converter (150) provided downstream of sensors (15) housed in the belt (1). The output of said AND gate is connected with the input of a D/A converter (72) which, on output, is connected with the means (2) which activate the inflation of the belt (1). Inserted on the line connecting the gate (70) with the converter (72) is a normally closed switch (71). Inserted on the line connecting the converter (150) with the converter (72) is a normally opened switch (73). When the sensors (15) sense an overpressure in the chamber of belt (1), a corresponding electrical signal is produced which, after being converted in digital form by the converter (150), is fed to the AND gate (70). Similarly, the signals on output from the section (6) of the electromyiographic apparatus (4) come to the AND gate (70) which, when both signals are present, activates, through the converter (72), the opening of a solenoid of means (2)

and, therefore, the inflation of the belt (1). The operator may decide to cut off the AND gate (70), for example in case of ascertained failure of the apparatus (4), by merely opening the switch (71) and closing the switch (73). The switches (71) and (73) operate in push-pull mode.

The said data processing section (6) can advantageously consist of a PC associated with the electromyiographic unit (4). Within the section (6), the signals coming from the sensors (3) and acquired by the system are processed according to a preset algorithm, for example, the one described in the article "A fast algorithm for detecting contractions in uterine electromyography - a non invasive method utilizing higher-order zero crossing for signal analysis" published in IEE Engineering and Biology - March/April 2000. Such an algorithm allows the obtainment of an estimator value to be compared with a predefined threshold. Throughout the time interval in which the estimator value exceeds said threshold, it is assumed that a contraction is taking place and a signal of logic level one is fed to the AND gate (70). Vice versa, when the estimator value is below said threshold value, a signal of logic level zero is fed to the AND gate (70).